

## **Remarks**

Claims 1-20 are in the case. All claims stand rejected. Claims 2, 7 and 12 have been amended to correct typographical errors. Formal drawings are enclosed. The grounds of rejection are traversed and reconsideration is respectfully requested.

## **Invention Disclosure Statement**

Applicant requests consideration of the references listed in the enclosed invention disclosure statement, including the favorable Written Opinion and International Search Report.

## **Objections to the Drawings**

The formal drawings submitted herewith are believed to address the objections concerning extraneous matter.

## **Claim Rejections – 35 USC § 112**

Claims 7 and 12 have been amended to correct the typographical errors that were noted by the Examiner.

## **Claim Rejections - 35 USC § 102**

Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kapandji (FR 2 660 856 A1). The Examiner takes the position that Kapandji discloses an implant 1 comprising a stem 20 and a head 4 (see Fig. 2), the implant having holes 26 passing through positions near both ends of the stem 20 and being capable of accepting a suture, and the head 4 including a 200 degree arc. The Examiner considers component 30 to be a portion of the platform or an extension, and further takes the position that component 30 includes holes 27 through which a suture could be passed.

Applicant traverses on grounds that a prima facie case of anticipation has not been established. It is respectfully suggested that Kapandji is being misinterpreted, and that Kapandji does not teach all of the limitations of the claimed invention. As can be seen in Figures 2, 3 and 4 of Kapandji, the cited reference teaches an implant that differs markedly in structure and function from that of the claimed invention. The Kapandji implant consists generally of a female

part 2, a fixation means 30 for the female part 2, a male part 3, and a fixation mean 7 for the male part. The female part 2 is implanted in a diaphyseal region of the ulna and is configured to articulate with the male part 3, which is implanted in a distal portion of the ulna. As shown in Kapandji Figures 3 and 4, the separate fixation means 7, 30 are configured to receive fixation screws 25, 44 in alignment with through bores in the stems 20, 40 of the respective female and male parts 2, 3. The Examiner interprets Kapandji component 4 as being a “head,” but this component of Kapandji is in fact an open cavity 4 (“cavité ouvert 4”) that is formed in a well 10 (“un puits 10”). The well 10 and its open cavity 4 are integrally formed with the stem 20 of the female part 2, and are configured to articulate with the head 5 of the male part 3, as clearly shown in Figures 3 and 4. Applicant respectfully suggests that Kapandji’s open cavity 4 cannot be interpreted as disclosing the head 14 of applicant’s claimed invention.

Kapandji clearly does not teach various other elements of at least claim 1, including at least the following. Kapandji does not teach an elongated stem “wherein suture holes are provided at or near the second end for receiving sutures attaching the implant to the soft tissue.” Nor does Kapandji teach “a head having a triangulated configuration.” As can be seen in Kapandji Figures 3 and 4, the head/open cavity 4 of Kapandji is clearly not “configured for mating with the sigmoid notch of the distal radius” since the head/open cavity 4 is positioned well above the sigmoid notch. Likewise, Kapandji does not teach “a head being further configured for attachment to the second end of the stem.”

Applicant notes that the International Search Report for the PCT counterpart of this application considered Kapandji as defining the general state of the art but not being of particular relevance to the claimed invention. (Please see the Information Disclosure Statement filed concurrently herewith).

Anticipation under 35 USC 102(b) requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindermann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984); MPEP § 2131. The prior art reference must be such that a person of ordinary skill in the field of the invention would consider there to be no difference between the claimed invention and the reference disclosure. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the prior art reference under 35 USC 102(b) must be enabling, thus placing the allegedly disclosed matter in SN 10/772,129

the possession of the public. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ.2d 1241, 1245 (Fed. Cir. 1986). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 48 USPQ.2d 1321, 1328 (Fed. Cir. 1998).

It is respectfully suggested that Kapandji does not teach each and every element of the claimed invention, and that Kapandji does not enable the claimed invention. Accordingly, a *prima facie* showing of anticipation has not been made.

#### **Claim Rejections - 35 USC § 103**

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooney, III et al. (6,302,915 B1) in view of Stubstad (3,745,590). The Examiner takes the position that Cooney discloses the claimed invention except for the use of suture holes in portions of the device other than the head and except for the head having a through-bore. The Examiner takes the position that Stubstad discloses a similar device 10 and teaches attaching a ligature or suture 22 through both the head 11 and the stem 16 platform 19 structure in order to provide a continuity of strength through the prosthesis and resist dislocation of the joint to be corrected while still providing unrestricted natural motion, citing Fig. 2; col. 1, lines 5-11; and col. 2, lines 44-47.

Applicant traverses on grounds that a *prima facie* showing of obviousness has not been established. Applicant does not agree with the Examiner's interpretation of Cooney and Stubstad. For example, as far as applicant can determine, neither Cooney nor Stubstad teach "a head having a triangulated configuration." In fact, Cooney specifically teaches a spherical structure for Cooney's head 12, as follows: "By cross-referencing FIGS. 1, 2 and 3A it can be seen that the head 12 is generally crown shaped and formed with a curved surface 18 for articulation with the sigmoid notch 20 of the distal radius 22." (Cooney, Col. 5, lines 4-8). As far as applicant can determine, Clooney provides no suggestion for providing any configuration for the head 12 other than spherical. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03, citing *In re Royka*,

490 F.2d 981, 180 USPQ 580 (CCPA 1974). For this reason alone, the proposed combination of Cooney in view of Stubstand fails to establish a *prima facie* case of obviousness.

Other claim elements are simply not found in the Cooney and Stubstad references, including for example “suture holes [26, 24] being provided at the proximal and distal ends of the extension [34]” and “the head includ[ing] a bore extending completely therethrough.” The Examiner takes the position that such missing elements are obvious, yet fails to point to any teaching, suggestion or motivation to combine the cited references in the manner of the claimed invention. Under the circumstances, it is respectfully suggested that applicant’s specification is being used as a blueprint to engage in hindsight reconstruction of the claimed invention.

The Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant of Cooney with holes in portions other than the head, such as the stem and platform, in view of Stubstad, in order to provide a continuity of strength through the prosthesis and resist dislocation of the joint to be corrected while still providing unrestricted natural motion. However, the Examiner points to nothing in the cited references that would suggest or teach the claimed combination. Although the Examiner takes the position that Stubstad teaches attaching a ligature or suture 22 through both the Stubstad head 11 and stem 16 platform structure 19, applicant can locate no such teaching, including in the portions of Stubstad that are cited by the Examiner (Fig. 2; col. 1, lines 5-11; and col. 2, lines 44-47). Stubstad discloses a unibody implant that clearly lacks many of the claimed features, such as an extension 34 and a head 14 configured for attachment to the extension 34. The Stubstad implant is for use in joints that require an unrestricted orbiting motion, such as the trapezium and lunate bones of the wrist. Stubstand makes no mention of the ulna or radius. Stubstand describes a unibody implant in which an affixed “ligamentous element” protrudes substantially along an edge of the articulating surface of the implant. Stubstad does not discuss providing holes in the implant, but instead consistently describes the ligamentous element as being integral with or affixed to the implant. By disclosing an affixed ligamentous element, Stubstad appears to teach away from providing a through bore for receiving a suture. Applicant fails to appreciate how Stubstand’s teaching of an implant having an integrally attached ligamentous structure somehow adds to the teaching of Cooney. It is therefore unclear to applicant how Stubstad can be interpreted as teaching or suggesting putting suture holes in both a head and stem, much less in the arrangement of the claimed invention.

With regard to the particular locations of the various holes, the Examiner takes the position that it also would have been obvious to have positioned these at any of various locations on the device, since it has been held that mere relocation of parts of an invention involves only routine skill in the art, citing *In re Japikse*, 86 USPQ 70. However, applicant is not merely relocating suture holes, but is claiming placement of the suture holes in the context of an implant that has a different structure and function from that of the cited references. The cited references simply do not teach, suggest or motivate the claimed arrangement.

The Examiner further takes the position that it would have been obvious to have selected a bore depth in the head within a range resulting in a through bore, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art, citing *In re Aller*, 105 USPQ 233. Applicant fails to appreciate how a through bore can be considered to be an optimum or workable range, when in fact a through bore is a different structure that enables different functions.

The Examiner bears the initial burden of factually supporting a prima facie conclusion of obviousness. MPEP § 2142. To establish a prima facie case of obviousness, the examiner must demonstrate: (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings; (2) a reasonable expectation of success; and (3) that the references teach or suggest all of the claim limitations. *Id.* The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *Id.* To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03, citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Because the cited references do not teach or suggest all of the claim limitations, and because there is no suggestion or motivation to combine the references in the manner of the claimed invention, it is respectfully suggested that a prima facie case of obviousness has not been established.

### **Conclusion**

For the foregoing reasons, applicant respectfully suggests that claims 1-20 are in a condition for allowance. It is believed that this response has been filed within the applicable time period for responding and that no extension of time is therefore required, but if an extension is required, applicant hereby requests an appropriate extension of time. It is further believed that no fees are due, but if any fees or credits are due, the Commissioner is authorized to charge or deposit them to Deposit Account No. 502795.

Respectfully submitted,

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